

## **REMARKS / ARGUMENTS**

Claims 1, 4-16 and 29-31 are pending and stand rejected. By the foregoing amendment, the applicants have amended claims 1, 5-7, 9, 11, 13 and 15 and canceled claims 4 and 31. No new matter is added by the amendments. In view of the foregoing amendments and following discussion, the applicants submit that all pending claims are in condition for allowance.

On page 3 of the Office Action the Examiner rejected claims 1, 4-16 and 29-31 on the ground of nonstatutory obviousness-type double patenting over claims 1-8 of U.S. Pat. No. 6,991,816 in view of Struengmann et al. (U.S. 6,284,269) in view of Mathiowitz (1999). The combination of the references does not result in amended claim 1. Amended claim 1 recites a film coated tablet having enhanced stability comprising: (a) 38% to 48% by weight of at least one excipient; (b) at least 50% by weight of a dried extract, the dried extract consisting essentially of ingredients of an aqueous extract of red vine leaves and greater than 1.4% to about 10% by weight of colloidal, anhydrous silica; and (c) 1% to 3% by weight of a tablet film; based on the total mass of the film coated tablet, wherein the dried extract of red vine leaves has been produced in a drying process comprising the step of adding silica during the drying process.

Neither the '816 patent nor Mathiowitz disclose a weight percentage of colloidal, anhydrous silica. Struengmann teaches a colloidal, anhydrous silica weight percent of 0.5% and 1.4% in Examples V/7 and V/10, respectively, which are outside of the claimed range and provides no reason or suggestion for a skilled artisan to increase the weight percent (cols. 10-12 of Struengmann). The combination of the references would result in a tablet having a colloidal, anhydrous silica weight percent of 0.5% or 1.4%. Therefore, the references do not result in the claimed invention.

Furthermore, the invention of amended claim 1 results in the unexpected superior stability of the claimed tablets. Enclosed herewith is a declaration under 37 C.F.R. § 1.132 by inventor Anke Esperester showing a comparison of the stability between the tablet of amended claim 1 and the stability of other tablets. Superior stability occurred in the instantly claimed tablets where the colloidal, anhydrous silica, 4% by weight of the dried extract, was added to the red vine leaf extract during the spray drying process. Thus the claimed tablets are superior over any tablet that could be made by a process according to the combination of the references. Therefore, the invention of amended claim 1 is not obvious over the '816 patent in view of

Struengmann in view of Mathiowitz and is therefore allowable. Claims 4-16 and 29-31 which depend from claim 1 and recite further limitations are also not obvious and are therefore allowable. Accordingly, the applicants request the Examiner withdraw the rejection.

On page 5 the Examiner rejected claims 1, 4-16 and 29-31 under 35 U.S.C. § 103(a) as being unpatentable over Bilgrami et al. (1993) in view of Struengmann in view of Mathiowitz. A skilled artisan would not combine the references in order to arrive at the claimed invention of amended claim 1. The proposed modification (i.e., a tablet form) to Bilgrami et al. in order to arrive at the claimed invention changes the principle of operation of Bilgrami et al. MPEP § 2142.02(VI) and *In re Ratti*, 270 F.2d 810 (CCPA 1959). Bilgrami discloses a comparative study between liquid supplements of hydrocortisone acetate, mercurious corrosivus and red vine leaves extract for their ability to control nephrotoxicosis. Bilgrami does not contemplate or provide any reason whatsoever to use film coated tablets. Struengmann teaches tablet additives including colloidal, anhydrous silica. Mathiowitz teaches controlled-released coatings (films) in tablet manufacture. To modify the 0.5 mL of the filtered aqueous leaf extract liquid supplement to achieve a film coated tablet containing dried red leaf extract, colloidal anhydrous silica and an excipient would change the principle under which the comparative study was designed to operate (i.e., the liquid supplement). Therefore, a skilled artisan would not combine the references in order to arrive at the claimed invention.

Furthermore, even if a skilled artisan were to combine the references, Struengmann and Mathiowitz fail to cure the deficiencies of Bilgrami. Bilgrami does not teach colloidal, anhydrous silica, let alone a weight percentage of colloidal, anhydrous silica greater than 1.4% to about 10%. Mathiowitz does not disclose a weight percentage of colloidal, anhydrous silica. Struengmann teaches a colloidal, anhydrous silica weight percent of 0.5% and 1.4% in Examples V/7 and V/10, respectively, which are outside of the claimed range and provides no reason or suggestion for a skilled artisan to increase the weight percent (cols. 10-12 of Struengmann). The combination of the references would result in a tablet having a colloidal, anhydrous silica weight percent of 0.5% or 1.4%. Therefore, the combination of the references cannot result in the claimed invention. Thus claims 1, 4-16 and 29-31 are not obvious over Bilgrami in view of Struengmann in view of Mathiowitz and are therefore allowable. Accordingly, the applicants request the Examiner withdraw the rejection.

On page 8 the Examiner rejected claims 1, 7, 9, 13, 29 and 30 under 35 U.S.C. § 103(a) as being unpatentable over Esperester et al. (WO 01/28363). The invention of Esperester does not teach or suggest the invention of amended claim 1. Amended claim 1 is recited above. Esperester discloses that “excipients” may optionally be added to the extract upon drying, but does not provide any reason for a skilled artisan to select silica. Furthermore, Esperester does not specifically include wherein the tablet is coated with a film nor provide any reason or suggestion for a skilled artisan to coat the tablets with a film-coating. The Examiner alleges that although Esperester did not disclose the claimed amounts of red vine leaf aqueous extract and colloidal silica, adjustment of the disclosed amounts in order to arrive at the claimed invention would be “well within the purview” of a skilled artisan. The applicants submit the superior effects of the claimed amounts would not be have been contemplated by the skilled artisan. In light of these deficiencies, a skilled artisan, without more, could not arrive at the claimed invention in light of Esperester. Therefore, the invention of amended claim 1 is not obvious over Esperester and is thus allowable. Claims 7, 9, 13, 29 and 30 which depend from claim 1 and recite further limitations are also not obvious and are therefore allowable. Accordingly, the applicants request the Examiner withdraw the rejection.

On page 10 the Examiner rejected claims 1, 4-16 and 29-31 under 35 U.S.C. § 103(a) as being unpatentable over Esperester et al. (WO 01/28363) in view of Bilgrami et al. in view of Struengmann et al. in view of Mathiowitz. For the same reasons above, a skilled artisan would not combine Bilgrami with the other references in order to arrive at the claimed invention, nor does the combination of the remaining references result in the invention of amended claim 1. A combination of Esperester, Struengmann and Mathiowitz would result in a film coated tablet with a colloidal, anhydrous silica weight percent of 0.5% or 1.4%. Furthermore, the superior effects of the claimed amounts would not be have been contemplated by the skilled artisan in light of the combination of the references. Therefore, the references do not result in the claimed invention. Thus, claim 1 is not obvious over Esperester in view of Bilgrami in view of Struengmann in view of Mathiowitz and is therefore allowable. Claims 4-16 and 29-31 which depend from claim 1 and recite further limitations are also not obvious and are therefore allowable. Accordingly, the applicants request the Examiner withdraw the rejection.

Applicants submit that all claims pending in the patent application are in condition for allowance. Accordingly, both reconsideration of this application and its swift passage to issuance are earnestly solicited. The fees for a RCE and a three-month extension of time are included herewith. In the event there are any fees due and owing in connection with this matter, please charge same to our Deposit Account No. 11-0223.

Respectfully submitted,

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